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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,498	10/27/2003	Richard J. Bucala	70015.0114USC1	2060

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EXAMINER	
BOWMAN, AMY HUDSON	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,498	BUCALA ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22-25* is/are pending in the application.

4a) Of the above claim(s) *2-4,7-9,11-13,16-20 and 22-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,10,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/9/04, 11/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of group IV, claims 1, 5, 6, 10, 14 and 15, in the reply filed on 8/23/2006 is acknowledged.

Applicant asserts that the search and examination of all currently pending claims would not pose an undue burden on the examiner. Although applicant asserts that there is not an undue burden upon the examiner, applicant does not provide any reasoning to come to this conclusion. As explained in the office action mailed on 6/26/2006, there is in fact an undue burden upon the examiner to search and examine the claims of groups I-VI and therefore restriction is proper.

The requirement for restriction is still deemed proper and is therefore made FINAL.

Claims 2-4, 7-9, 11-13, 16-20, and 22-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/23/2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention of the above claims is drawn to a compound that inhibits or neutralizes the biological activity of MIF. The invention is further drawn to a pharmaceutical composition comprising the compound and a carrier.

At the outset, it is noted that the instant claims are directed to any compound that inhibits or neutralizes the biological activity of MIF.

The claims encompass a multitude of possible compounds, including small molecule inhibitors, dsRNA duplexes, miRNAs, as well as encompass any other compound that would inhibit or neutralize the biological activity of MIF.

Although the specification discloses anti-MIF antibodies, antisense molecules, and ribozymes as agents that inhibits or neutralizes the biological activity of MIF, the specification does not describe any other therapeutic agent that is effective to inhibit or neutralize the biological activity of MIF to describe the instantly claimed genus of any compound that inhibits or neutralizes the biological activity of MIF.

Given the breadth of agents embraced in the instantly claimed genus, one could not envision the member genus of agents so that the skilled artisan would recognize that the applicant was in possession of the claimed genus at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 10, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Fahlbusch et al. (Biomed Biochim Acta, 1987, 46(5), pages 397-406).

The invention of the above claims is drawn to a compound, more specifically an anti-MIF antibody that inhibits or neutralizes the biological activity of MIF. The invention is further drawn to a pharmaceutical composition comprising the anti-MIF antibody and a carrier. Instant claim 15 is drawn to a pharmaceutical composition comprising a therapeutically effective amount of a fragment or derivative of an antibody, wherein the fragment or derivative contains the binding domain of the antibody. It is noted that a composition comprising an anti-MIF antibody meets the limitations of a composition comprising a fragment of the antibody.

Fahlbusch et al. teach generation of a monoclonal antibody specific for human MIF. The antibodies neutralized the biological activity of ovarian cancer MIF. Furthermore, Fahlbusch et al. teach that the anti-MIF antibody was coupled with the carrier Sepharose 4B in a composition (see abstract).

Therefore, the instant invention is anticipated by Fahlbusch et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 6, 10, 14 and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,645,493 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of patent '493 anticipate the claims of the instant invention.

The invention of the above claims is drawn to a compound, more specifically an anti-MIF antibody that inhibits or neutralizes the biological activity of MIF. The invention is further drawn to a pharmaceutical composition comprising the anti-MIF antibody and a carrier.

Patent '493 recites a pharmaceutical composition comprising an anti-MIF antibody in a suitable pharmaceutical carrier, wherein the antibody binds to and neutralizes biological activity of MIF and the antibody is present in an amount suitable for administration to a patient in a therapeutically effective dosage.

Therefore, the instant claims are anticipated by claim 1 of patent '493.

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,774,227 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of patent '227 anticipate the claims of the instant invention.

The invention of the above claims is drawn to a compound that inhibits or neutralizes the biological activity of MIF. The invention is further drawn to a pharmaceutical composition comprising the compound and a carrier.

Patent '227 recites an antisense molecule that is complementary to MIF mRNA. The antisense molecule of patent '227 anticipates the broad genus of instant claim 1.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AHB

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER